PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Can training, in advanced clinical skills in obstetrics, neonatal care
	and leadership, of non-physician clinicians, in Malawi, impact on
	clinical services improvements (The ETATMBA Project): A process
	evaluation
AUTHORS	Ellard, David; Chimwaza, Wanangwa; Davies, David; O'Hare, Paul;
	Kamwendo, Francis; Quenby, Siobhan; Griffiths, Frances

VERSION 1 - REVIEW

REVIEWER	Tim Colbourn,
	Lecturer in Global Health Epidemiology and Evaluation
	UCL Institute for Global Health, UK
REVIEW RETURNED	12-Jun-2014

GENERAL COMMENTS	Thanks for the opportunity to review this paper on the process evaluation of an interesting and useful training intervention in Malawi. I have a couple of major comments and quite a few minor comments that I think if addressed could improve the paper.
	Major comments 1. You don't report any negative findings. Were the NPCs asked
	about negative aspects of the intervention? Or what they think could have been done better or instead?
	2. Although I appreciate the trial results will show impact, I think the paper could be greatly enhanced with an attempt to link casefatality rates for different complications (e.g. eclampsia, PPH, neonatal asphyxia) to the doses delivered and received in each intervention facility. Simple run-charts showing the complication specific case-fatality rates by month annotated with the dosage of the specific interventions by month for each facility would greatly enhance and corroborate (or not) the very positive qualitative process evaluation you report.
	Minor comments 1. Abstract, results, line 24: it's not clear what you mean by
	"remaining" – do you mean the other 8 dropped out of the

intervention?

- 2. Abstract, lines 24 & 28 and throughout the paper: "District" should be "district".
- 3. Strengths and limitations, point three: "both the lives have been saved, both mothers and babies" needs rephrasing.
- 4. Strengths and limitations, point four: insert "a" at the end of the first line.
- 5. Introduction, paragraph 4 (and discussion third paragraph): Could add these two references:

van Amelsfoort JJ, van Leeuwen PA, Jiskoot P, et al. Surgery in Malawi—the training of clinical officers. Trop Doct 2010;40:74–6.

Wilhelm TJ, Thawe IK, Mwatibu B, et al. Efficacy of major general surgery performed by non-physician clinicians at a central hospital in Malawi. Trop Doct 2011;41:71–5.

6. Introduction: you could also briefly add details of this recent study showing lack of knowledge of maternal and neonatal care in non-physician clinicians in Malawi, which provides relevant context to your intervention:

Bayley O, Colbourn T, Nambiar B, Costello A, Kachale F, Meguid T, Mwansambo C: Knowledge and perceptions of quality of obstetric and newborn care of local health providers: a cross-sectional study in three districts in Malawi. Malawi Medical Journal 2013, 25:110-113.

Note that although this paper was published in December 2013, for some reason it has not yet been archived to appear on PubMed yet. It is however, available for free download here: http://www.ajol.info/index.php/mmj/article/view/102068/92113

- 7. Page 4, line 48: replace "was two-year plus" with "was a two-year plus"; or better still replace with number of months duration.
- 8. Page 6, first line: punctuation needs redoing for the sentence to make sense
- 9. Page 6, lines 4-5 of text, starting "We interviewed...": this is repetition of the first sentence of this page.
- 10. Page 6, line 12: "cascadee" this is an unfamiliar term that would benefit from being better explained at first use.
- 11. Page 6, line 26: "Data was drawn for [note typo should be "from"?] Malawi Ministry of Health (MOH) documents": please

reference these documents.

- 12. Page 6, line 46: replace "refined" with "were refined"
- 13. Page 6, lines 42-43: sentence about process evaluation framework used and how it relates to Table 1 is not clear.
- 14. Page 9, line 17: add percentage after 46: (85%) to show attrition.
- 15. Page 9, line 23: "reflecting the gender balance" please either state what the gender balance of NPCs is in Malawi and reference the source, or reference a source here.
- 16. Page 9, Dose Delivered, lines 32-37: were all these skills supported for all trainees in all hospitals? If not please state numbers and % of trainees supported with each skill or show in a table.
- 17. Page 9, line 52: "with 19 trainees as we report on later interview data in subsequent sections" this isn't really a convincing justification for only reporting on dose received for 19 trainees. Did you ask about dose received in the other interviews too? If so, why not report this data too?
- 18. Page 9, lines 53-57: were all these reports of training received un-prompted?
- 19. Page 10, third line: "(see box 1)" should before "." Same for box 2 on page 12, line 15.
- 20. Page 11, Practical skills section this seems to overlap with the dose received section on page 9 (see my comment 17. above); given this section has more detail, is the earlier section needed?
- 21. Page 12, line 11: "virginal" or "vaginal"?
- 22. Page 15, line 9: references [24-27] you could also add this reference it is a peer-reviewed technical report containing a lot of process evaluation of a quality improvement in maternal and neonatal care intervention in Malawi:

Colbourn T, Nambiar B, Costello A: MaiKhanda - Final evaluation report. The impact of quality improvement at health facilities and community mobilisation by women's groups on birth outcomes: an effectiveness study in three districts of Malawi. Available at http://www.health.org.uk/publications/maikhanda/ (accessed 12/06/2014). pp. 1-364. London: The Health Foundation; 2013:1-364.

Please note the trial paper is published:

Colbourn T, Nambiar B, Bondo A, Makwenda C, Tsetekani E, Makonda-Ridley A, Msukwa M, Barker P, Kotagal U, Williams C, et al: Effects of quality improvement in health facilities and community mobilisation through women's groups on maternal, neonatal and perinatal mortality in three districts of Malawi: MaiKhanda, a cluster randomised controlled effectiveness trial. International Health 2013, 5:180-195.

But the process evaluation journal papers are still being written-up.

- 23. Discussion you could add a lot more on different methods of training and quality improvement (e.g. see above) and how your method compares to these.
- 24. Page 15, last sentence: this sentence is too long and could be better expressed (e.g. "previously much neglected clinical resource" not clear what you're referring to here).
- 25. Data sharing statement: "No additional data is available" don't you have the complete transcripts for all the interviews?
- 26. Supplementary appendix, page 1: the web address requires University of Warwick access, please replace with a website that anyone can freely access.

REVIEWER	jogchum Beltman
	Leiden Universtity Medical Centre
	The Netherlands
REVIEW RETURNED	16-Jun-2014

GENERAL COMMENTS

this is an intresting paper which discusses the possibility to change clinical practise in obstetrics by educational intervention. Such qualitive studies are very important to identify factors contributing to the high maternal morbidity/mortality, but also provide insight in perceptions of health care workers regarding (sub)standard care.

Still I have some remarks/questions which the authors probably can explain:

- in the introduction part, it is rightly stated that there are no clear career pathways for NPCs who are often undervalued. By training them in such way it is decribed in the paper, NPCs wil receive more tasks. Not only they are clinicians, but they will become teachers, lead audits, show leadership, etc. In ohter words: the already heavily burdened health care workers will receive new tasks for which who will pay for? Will he receive better career pathways by committing to such a program?
- It is not clear if trainees will stay in the hospitals in order to measure progress after some time. What if the hospitals fails to

retain NPCs?
- page 12: virginal should be vaginal

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Major comments

- You don't report any negative findings. Were the NPCs asked about negative aspects of the intervention? Or what they think could have been done better or instead?
 In the results section we have reported numbers of NCPs. This demonstrates that the intervention did not have the same impact across the whole cohort. We have added a sentence in the discussion section drawing the reader's attention to this.
- 2. Although I appreciate the trial results will show impact, I think the paper could be greatly enhanced with an attempt to link case-fatality rates for different complications (e.g. eclampsia, PPH, neonatal asphyxia) to the doses delivered and received in each intervention facility. Simple runcharts showing the complication specific case-fatality rates by month annotated with the dosage of the specific interventions by month for each facility would greatly enhance and corroborate (or not) the very positive qualitative process evaluation you report.

Thank you for this suggestion. As you say the trial results will be what show impact or not. The suggestion of linking case-fatality rates to the doses delivered and received is very interesting. However, we do not have sufficient detail of data available at this stage to do this.

Minor comments

1. Abstract, results, line 24: it's not clear what you mean by "remaining" – do you mean the other 8 dropped out of the intervention?

We have edited the abstract to enable us to clarify this within the word limit

2. Abstract, lines 24 & 28 and throughout the paper: "District" should be "district".

Thank you: All changed

3. Strengths and limitations, point three: "both the lives have been saved, both mothers and babies" needs rephrasing.

Thank you: we have re-phrased

- 4. Strengths and limitations, point four: insert "a" at the end of the first line.
 - Thank you: updated
- 5. Introduction, paragraph 4 (and discussion third paragraph): Could add these two references:

 Thank you: Both entered
- van Amelsfoort JJ, van Leeuwen PA, Jiskoot P, et al. Surgery in Malawi—the training of clinical officers. Trop Doct 2010;40:74–6.
- Wilhelm TJ, Thawe IK, Mwatibu B, et al. Efficacy of major general surgery performed by non-physician clinicians at a central hospital in Malawi. Trop Doct 2011;41:71–5.
- 6. Introduction: you could also briefly add details of this recent study showing lack of knowledge of maternal and neonatal care in non-physician clinicians in Malawi, which provides relevant context to your intervention:

Thank you: We have added

Bayley O, Colbourn T, Nambiar B, Costello A, Kachale F, Meguid T, Mwansambo C: Knowledge and

perceptions of quality of obstetric and newborn care of local health providers: a cross-sectional study in three districts in Malawi. Malawi Medical Journal 2013, 25:110-113.

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http://www.ajol.info/index.php/mmj/article/view/102068/92113

7. Page 4, line 48: replace "was two-year plus" with "was a two-year plus"; or better still replace with number of months duration.

Thank you: We have edited to total months

- 8. Page 6, first line: punctuation needs redoing for the sentence to make sense
 We have edited this to make it clearer. Thank you
- 9. Page 6, lines 4-5 of text, starting "We interviewed...": this is repetition of the first sentence of this page.

Thank you: Removed

10. Page 6, line 12: "cascadee" – this is an unfamiliar term that would benefit from being better explained at first use.

Thank you. We have explained at first use

11. Page 6, line 26: "Data was drawn for [note typo – should be "from"?] Malawi Ministry of Health (MOH) documents": please reference these documents.

Thank you: updated

12. Page 6, line 46: replace "refined" with "were refined"

Thank you: updated

13. Page 6, lines 42-43: sentence about process evaluation framework used and how it relates to Table 1 is not clear.

Thank you: we have edited this

14. Page 9, line 17: add percentage after 46: (85%) to show attrition.

Thank you: updated

15. Page 9, line 23: "reflecting the gender balance" – please either state what the gender balance of NPCs is in Malawi and reference the source, or reference a source here.

Thank you: we have edited to clarify

16. Page 9, Dose Delivered, lines 32-37: were all these skills supported for all trainees in all hospitals? If not please state numbers and % of trainees supported with each skill – or show in a table.

Thank you. We have edited to clarify

17. Page 9, line 52: "with 19 trainees as we report on later interview data in subsequent sections" — this isn't really a convincing justification for only reporting on dose received for 19 trainees. Did you ask about dose received in the other interviews too? If so, why not report this data too? We have reviewed our text in the light of this comment. In the methods we explain that we asked about what the trainees learnt in the other interviews. In the results we state 'In all interviews with trainees we found them able to recall unprompted, some components of the training modules'. In the results we have also added an explanation as to why we do not include subsequent interview data in this section.

18. Page 9, lines 53-57: were all these reports of training received un-prompted?

Thank you: Yes they were. The interview schedules for these early interviews included no examples or specific prompts. Some text has been added

- 19. Page 10, third line: "(see box 1)" should before "." Same for box 2 on page 12, line 15.

 Thank you: updated
- 20. Page 11, Practical skills section this seems to overlap with the dose received section on page 9 (see my comment 17. above); given this section has more detail, is the earlier section needed?In this section we are reporting the skills used in practice. We are also demonstrating that not all the trainees who learnt the skills reported implementing them in practice.
 - 21. Page 12, line 11: "virginal" or "vaginal"? Thank you: we have edited this.
 - 22. Page 15, line 9: references [24-27] you could also add this reference it is a peer-reviewed technical report containing a lot of process evaluation of a quality improvement in maternal and neonatal care intervention in Malawi:

Colbourn T, Nambiar B, Costello A: MaiKhanda - Final evaluation report. The impact of quality improvement at health facilities and community mobilisation by women's groups on birth outcomes: an effectiveness study in three districts of Malawi. Available at

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But the process evaluation journal papers are still being written-up.

Thank you: We have added these to our references of process evaluations and included the trial within out discussion section.

23. Discussion – you could add a lot more on different methods of training and quality improvement (e.g. see above) and how your method compares to these.

Thank you. We have added a comment that a limitation of our intervention is its focus on NCPs.

24. Page 15, last sentence: this sentence is too long and could be better expressed (e.g. "previously much neglected clinical resource" – not clear what you're referring to here).

Thank you: we have edited this to make it clearer

- 25. Data sharing statement: "No additional data is available" don't you have the complete transcripts for all the interviews?
- When we set up the project we did not seek consent from interviewees for data sharing. This was an oversight but we are unable to remedy this now.
- 26. Supplementary appendix, page 1: the web address requires University of Warwick access, please replace with a website that anyone can freely access.

Thank you: Yes this was an error we had included an incorrect URL, this has now been updated

Reviewer two

This is an interesting paper which discusses the possibility to change clinical practise in obstetrics by educational intervention. Such qualitative studies are very important to identify factors contributing to the high maternal morbidity/mortality, but also provide insight in perceptions of health care workers regarding (sub) standard care.

Still I have some remarks/questions which the authors probably can explain:

- in the introduction part, it is rightly stated that there are no clear career pathways for NPCs who are often undervalued. By training them in such way it is described in the paper, NPCs will receive more tasks. Not only they are clinicians, but they will become teachers, lead audits, show leadership, etc. In other words: the already heavily burdened health care workers will receive new tasks for which who will pay for? Will he receive better career pathways by committing to such a program? Thank you for this comment. The paper clarifies that the NCPs receive a qualification at the end of the programme. The NCPs were keen to have this qualification. We agree that NCPs are already burdened by their health care work. However, we audit, teaching skills to colleagues, providing clinical leadership by for example encouraging team work and checking supplies are all normal parts of quality clinical practice for all health professionals.

- It is not clear if trainees will stay in the hospitals in order to measure progress after some time.

What if the hospitals fails to retain NPCs?

We have added to the discussion section that a limitation of the intervention is its focus on the NCPs who may not stay in the same clinical work place.

page 12: virginal should be vaginal
 Thank you: updated